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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,592	09/30/2003	Sergey Dzekunov	MAXC:014US	9928
32425 7590 03/09/2007 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER FERNANDEZ, SUSAN EMILY	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/675,592	<b>Applicant(s)</b> DZEKUNOV, SERGEY	
	<b>Examiner</b> Susan E. Fernandez	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 17-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,11 and 14-16 is/are rejected.
- 7) ☒ Claim(s) 3,9,10,12,13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

A pre-appeal brief request for review was filed on November 13, 2006. As an outcome of the conference, the rejection and the finality of the previous office action have been withdrawn.

Claims 1-33 are pending. Claims 17-33 are withdrawn.

Claims 1-16 are examined on the merits.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-8, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Calvin (US 5,098,843) in light of Torr et al. (US 6,891,712).

One of the embodiments taught in the Calvin patent is a continuous flow electroporation method wherein cell suspensions are pumped through an electroporation chamber shaped so that "...the high intensity electrical field to which the cells are exposed varies in intensity..." (column 7, lines 22-34). Figures 5 and 6 demonstrate this embodiment of the Calvin patent. Given that the electric field is created by a pair of electrodes shaped to line a venturi passage (column 8, lines 4-12 and see 100a and 100b on Figure 6), the electric field generated is inherently spatially inhomogeneous. See Torr et al., column 5, lines 31-37, which points out that

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inhomogenities of electric field lines can be achieved with a system of electrodes with curvature to the surfaces.

In the practice of continuous flow electroporation in a continuous flow electroporation chamber, "...a potential of 600 volts DC is **maintained** by power source...on the electrodes within the chamber" (column 7, lines 58-62, emphasis added). Since the voltage is maintained at 600 volts DC, the electric field is substantially constant in magnitude and the electrodes are continuously energized while the cell suspensions traverse the electric field. Moreover, Calvin even points out that "where continuous flow methodology is practiced, the desired effects of a transient high intensity electric pulse are simulated by varying and controlling the flow rates of the cell suspension as such suspension travels through an electroporation chamber having a venturi shaped passageway including appropriately shaped electrodes impressed with a high level of DC voltage" (column 2, lines 61-68, and see also column 8, lines 35-41). Clearly electric pulses are not applied to the suspension while it traverses the electroporation chamber as the act of sending the suspension through the chamber simulates an electric pulse. Thus, instant claims 1, 2 (electrodes must be couple to DC source in order to provide DC voltage), 6 (duty cycle must be about 100% in order to maintain a potential of 600 volts DC), 7, 8, and 16 are anticipated by Calvin.

A holding of anticipation is clearly required.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-8, 11, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvin in light of Torr et al.

As discussed above, Calvin (in light of Torr et al.) anticipates claims 1, 2, 6-8, and 16. However, Calvin does not expressly disclose the peak and average power consumptions or a voltage of 100-150 volts. Nevertheless, the selection of specific suitable peak and average power consumptions and voltages, including those claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill in the art, as the poration of cell membranes would have been affected by the applied electric field. Moreover, Calvin teaches that "the field strength at which maximum transformation occurs is determined by the cell type and the concentration at which the cells are suspended in the transformation buffer" (column 6, lines 61-64). Thus, instant claim 4, 5, 11, 14, and 15 are rendered obvious by the reference.

### ***Response to Arguments***

Applicant's arguments filed November 13, 2006, with respect to the rejection of claims 1-16 under 35 U.S.C. 112, second paragraph, 35 U.S.C. 102(b), and 35 U.S.C. 103(a) over the prior art references Muller et al., Baumann et al., and Acker, have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Calvin in light of Torr et al., as discussed above.

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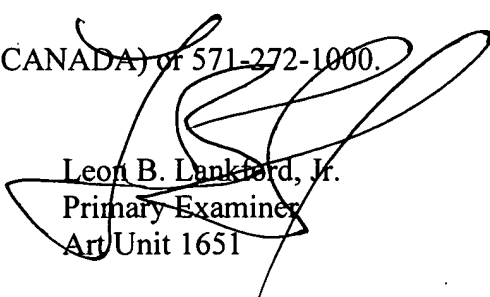
No claims are allowed. Claims 3, 9, 10, 12, and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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